UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,196	03/06/2001	Kai Wang	240083.509	4095

7590 02/25/2003

JAMES M.VERNA ESQ.
SEED INTELLECTUAL PAROPERTY LAW GROUP PLLC
701 FIFTH AVENUE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER	
SOUAYA, JEHANNE E	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 02/25/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/801,196	Applicant(s) Wang et al
	Examiner Jehanne Souaya	Art Unit 1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 6, 2001* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-24* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 5-7 drawn to polynucleotides and vectors and host cells comprising polynucleotides, classified in class 536, subclass 23.1, class 435, subclass 320.1, and class 435, subclasses 243 or 325, respectively.

II. Claims 2, 13, and 22-24, drawn to polypeptides, classified in class 530, subclass 350.

III. Claims 9-10, drawn to antibodies, classified in class 530, subclass 387.1.

IV. Claims 12-14, drawn to methods of detecting polynucleotides, classified in class 435, subclass 6.

V. Claim 12, drawn to methods of detecting polypeptides, classified in class 435, subclass 7.1.

VI. Claim 8, drawn to a method of producing a polypeptide comprising culturing the host cell comprising a polynucleotide sequence encoding the polypeptide under conditions sufficient to express the polypeptide in the cell and isolating the polypeptide, classified in class 435, subclass 71.1.

VII. Claim 11, drawn to a hybridoma which produces an antibody, classified in class 435, subclass 346.

VIII. Claims 17 and 18a-18b, drawn to a method of inhibiting the expression of a polypeptide using gene therapy, classified in class 514, subclass 44.

IX. Claims 15, 17, 18c, and 20, drawn to a method of inhibiting the expression of a polypeptide using antisense, classified in class 536, subclass 24.5.

X. Claims 14, 17, and 19, drawn to a method of inhibiting the expression of a polypeptide using a ribozyme, classified in class 536, subclass 24.5.

XI. Claim 21, drawn to a method of inhibiting hair growth, classified in class 424, subclass 114.

Claim 17 link(s) inventions VIII, IX, and X. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 17. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

2. The inventions are distinct, each from the other because of the following reasons:

The inventions of groups I, II, III, and VII, are patentably distinct from each other because they are drawn to different products having different structures and functions. The nucleic acid of group I is composed of deoxyribonucleotides linked by phosphodiester bonds and assumes the form of a double helix. The polypeptide of group II is composed of amino acids linked by peptide bonds and can assume complex tertiary structures. While the antibody of group III is also composed of amino acids linked by peptide bonds, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer. The hybridoma of group VII is unrelated structurally to the nucleic acids, peptides, and antibodies, as it is composed of cellular material. The products of groups I-III and VII can be used in materially different processes, for example the DNA of group I can be used to express a protein or as primers in PCR assays, the antibody of group III can be used in immunoassays, the polypeptide of group II can be used to make a fusion protein, and the hybridoma of group VII can be used to make antibodies. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of groups I - III and VII are patentably distinct from each other.

The inventions of groups I and IV, VIII, IX, and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of group I can be used to express proteins which is not required for the methods of group IV, VIII, IX, & X.

The invention of group I is not related to the invention of group V or XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotide of group I is not used in the methods of group V or XI.

The inventions of group I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of group I can be used to make probes and primers for detection and amplification purposes.

The invention of group II is unrelated to the inventions of groups IV, VIII, IX, X and XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide of group II is not used in the method of detecting a polynucleotide of group IV, the method of gene therapy of group VII, the

antisense method of group IX, or the ribozyme method of group X, and the method of inhibiting hair growth of group XI.

The inventions of groups II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of group II can be used to make fusion proteins with enzymatic functions which are not required for the method of detection of group V.

The inventions of groups II and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide of group II can be made synthetically and does not have to be made using the process of group VI.

The invention of group III is unrelated to the inventions of groups IV,VI, and VIII-XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibodies of group II are not used in the method of detecting a polynucleotide of group IV, the method of producing a polypeptide of

group VI, the methods of inhibiting expression of groups VIII-X, or the method of inhibiting hair growth of group XI

The inventions of groups III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of group III can be used in immunoassays which are not required for the method of detection of group V (the compound that binds to the polypeptide can be a specific ligand for the polypeptide).

The inventions of groups IV-VI and VIII-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of detecting polynucleotides of group IV, the method of detecting polypeptides of group V, the method of producing a polypeptide of group VI, the methods of inhibiting polypeptide expression of group VIII using gene therapy, the method of inhibiting polypeptide expression of group IX using antisense molecules, the method of inhibiting polypeptide expression of group X using ribozymes, and the method of inhibiting hair growth of group XI have different modes of operation, different functions, and different effects. Each method requires different reagents, reaction conditions, and reaction parameters. Further, the inventions of groups IV-VI and VIII-XI are unobvious over one another.

Inventions IV, V and VI are unrelated to invention VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects. The hybridoma of group VII is not used in the method of detecting polynucleotides of group IV, the method of detecting polypeptides of group V, or the method of producing a polypeptide of group VI.

Inventions VII and VIII-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions different modes of operation, different functions, and different effects. The hybridoma of group VII is not used in any of the methods of groups VIII-XI.

3. Upon election of a group above, applicant is further required to elect a single, patentably distinct nucleic acid or polypeptide sequence. This is NOT an election of species. Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary (it cannot be determined, for example, how SEQ ID NO 1 and SEQ ID NO 3 or SEQ ID NO 1 and SEQ ID NO 5 are related to each other), each such nucleotide sequences are presumed to

represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141.

By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a).

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and the search required for a single group is not required for the remaining groups, restriction for examination purposes as indicated is proper.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Patent examiner
Art Unit 1634
2/20/03